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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,546

Applicant(s)

DUHOT ET AL.

Examiner

Elizabeth McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,12-14,16-21,23,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 3,8 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,7,12-14,17-21,23,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. In response to applicants traverse and the amendment of the claims filed December 12, 2001 and March 12, 2002, the Examiner has regrouped the claims of Groups I, II IV and VII. The claims of Groups VI and VIII-X have been cancelled. Claims 3, 8 and 16 of Groups III, V and IX are withdrawn as drawn to non-elected inventions. The traversal is on the ground(s) that there would be no undue burden in the search and examination of the additional claims. This is not found persuasive because there would be an undue burden in the search and examination of the additional claims that require cotransformation with the additional nucleic acid sequence encoding SAM, as stated in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4, 6, 7, 12-14, 17-21, 23, 30 and 31 are drawn to the elected invention and are examined in the instant office action.

Claims 3, 8 and 16 are withdrawn as drawn to non-elected inventions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 12 and 19, and claims 2, 6, 7, 13, 14, 17-18, 20, 21, 23, 30 and 31 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and all claims dependent thereon, are indefinite and confusing in the recitation of "one plant material", since it is unclear what would constitute "one plant material".

Claim 1 is also indefinite for failing to recite any method steps for the process claimed.

5 Claims 1 and 12, and all claims dependent thereon, are indefinite in the recitation of "permitting transfer", since it is unclear what this means in the context of an enzyme reaction. "To permit" requires judgement, which would not pertain to an enzyme reaction. If "catalyzing" is intended and is supported in the specification, then amendment of the claims to substitute this would overcome the rejection.

10 Claim 4 is indefinite in the recitation of "a product which induces or stimulates the post-synthetic branching", since it fails to further limit the subject matter of claim 1. In addition, there is no antecedent basis for the claimed product, unless that product is the enzyme recited in claim 1.

15 Claim 19 is indefinite in the recitation of "oleaginous", since this can be defined either as relating to olive trees or as relating to oil, and it is unclear which is intended. Furthermore, if the second definition is intended, then it is unclear how it would further limit the claim, since all plant cells make oil in some form.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 12-14, 17-21, 23, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5 The claims are drawn to a process for producing branched fatty acids in a plant cell, plant material or a plant that comprises a recombinant nucleic acid coding for an enzyme that causes the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty acid. However, the specification only discloses the use of a cyclopropane fatty acid synthase gene transformed into a plant cell to produced branched fatty acids. The specification does not
10 teach any other genes that encode enzymes that would function in the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty acid to produce a branched fatty acid in a plant. In addition, the specification does not teach structural features that would be required for the claimed genus.

 See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir.
15 1997), where it states:
 “The name cDNA is not in itself a written description of that
DNA; it conveys no distinguishing information concerning its
identity. While the example provides a process for obtaining
human insulin-encoding cDNA, there is no further information in
20 the patent pertaining to that cDNA’s relevant structural or
physical characteristics; in other words, it thus does not describe
human insulin cDNA . . . Accordingly, the specification does not
provide a written description of the invention . . .”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

5 Claims 1, 2, 4, 6, 12-14, 17-21, 23, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transforming tobacco with a cyclopropane fatty acid synthase gene to produce branched fatty acids in a plant, does not reasonably provide enablement for the production of branched fatty acids in any plant with any gene that encodes an enzyme that will transfer one or more alkyl groups to the double bond of
10 an unsaturated fatty acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

 The claims are drawn to a process for producing branched fatty acids in a plant cell, plant material or a plant that comprises a recombinant nucleic acid coding for an enzyme that
15 causes the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty acid. However, the specification only discloses use of a cyclopropane fatty acid synthase gene transformed into a plant cell to produce branched fatty acids. No other genes are disclosed that are demonstrated to produce a branched fatty acid in a plant cell. In addition, no guidance is provided for obtaining other genes that will produce branched fatty acids in a plant cell.

20 More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty

acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, even if sequences are identified that have similarity to other sequences may transfer an alkyl group to the double bond of a fatty acid, one cannot conclude that these other sequences also encode enzymes that will produce a branched fatty acid. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in the synthesis of fatty acids is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding enzymes that can transfer an alkyl group to the double bond of a fatty acid, and the modification of plant lipid composition by transforming a plant with said gene are highly unpredictable.

Therefore, given the lack of working examples of genes other than a cyclopropane fatty acid synthase gene transformed into plant cells to produce branched fatty acids; the lack of working examples of producing branched fatty acids in a plant other than tobacco; the absence of guidance in the specification with regard to obtaining and using other genes that will produce a branched fatty acid in a plant cell, including those other than tobacco; and given the high level of unpredictability of obtaining other genes and modifying fatty acids in plant cells,

as stated above; and given the breadth of the claims which encompass the use of any gene that encodes an enzyme that can transfer an alkyl group to the double bond of a fatty acid in any species of plant cell; it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

20

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 7 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmid (Plant Lipid Metabolism, 1995, in the IDS).

The claims are drawn to a process for producing branched fatty acids in a plant cell, plant material or a plant that comprises a recombinant nucleic acid coding for an enzyme that causes the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty acid, including use of a cyclopropane fatty acid synthase gene transformed into cells and
5 extracting branched fatty acids from the cells or medium.

Schmid (Plant Lipid Metabolism, 1995, in the IDS) teaches a process for producing branched fatty acids in a plant cell comprising transforming plant cells with a gene encoding cyclopropane fatty acid synthase and extracting branched fatty acids from the cells.

10 Claims 1, 2, 4, 7, 12, 13, 17-21, 23, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Schmid (U.S. Patent 5,936,139).

The claims are drawn to a process for producing branched fatty acids in a plant cell, plant material or a plant that comprises a recombinant nucleic acid coding for an enzyme that causes the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty
15 acid, including use of a seed specific promoter.

Schmid (U.S. Patent 5,936,139) teaches a process for producing branched fatty acids in a plant cell comprising transforming plant cells of an oilseed crop with a gene encoding cyclopropane fatty acid synthase operably linked to a seed specific promoter (column 4), and extracting branched fatty acids from the cells (column 6). Schmid (U.S. Patent 5,936,139)
20 also teach that the oilseed crop may be sunflower or peanut, for example (column 4, lines 42-55).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various
10 claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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see intro/summary
1, 2, 4, 7, 12, 13, 17-^{and} 19, 31
Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid (Plant Lipid Metabolism, 1995, in the IDS) taken with Benfey et al (U.S. Patent 5,110,732).

The claims are drawn to a process for producing branched fatty acids in a plant cell, plant material or a plant that comprises a recombinant nucleic acid coding for an enzyme that
20 causes the transfer of one or more alkyl groups to the double bond(s) of an unsaturated fatty acid that is operably linked to a tissue specific promoter, such as a seed specific promoter, including use of a cyclopropane fatty acid synthase gene transformed into cells and extracting branched fatty acids from the cells or medium.

Schmid (Plant Lipid Metabolism, 1995, in the IDS) teaches a process for producing branched fatty acids in a plant cell comprising transforming plant cells with a gene encoding cyclopropane fatty acid synthase and extracting branched fatty acids from the cells. In addition, Schmid teaches the desirability of expressing the CFA enzyme in the seeds of the plant and that alternative promoters could be used to enhance the expression in seeds.

Schmid does not specifically teach use of a seed specific promoter and extraction of branched fatty acids from seeds.

Benfey et al teach a seed specific promoter derived from the CaMV 35 S promoter (see column 4, at least).

Given the teachings of Schmid of the transformation of plant cells with a cyclopropane fatty acid synthase gene for the purpose of producing branched fatty acids in plant cells, it would have been obvious to use the methods taught by Schmid and to modify them by substituting the seed specific promoter fragment of the CaMV 35 S promoter, as taught by Benfey et al, given the motivation provided by Schmid to enhance the production of the CFA enzyme in the seeds for seed oil production enhanced for branched fatty acids. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475, or to the Group receptionist whose telephone number is (703) 308-0196.

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Elizabeth F. McElwain, Ph.D.
September 9, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800